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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,873	11/06/2001	Lawrence M. Souza	01017/36370A	8203

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/992,873

Applicant(s)

SOUZA, LAWRENCE M.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 1/2, 3. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Election/Restriction***

Applicant's election without traverse of Group II in Paper No. 8 (30 January 2003) is acknowledged.

### ***Status of Application, Amendments, And/Or Claims***

The preliminary amendments filed 06 November 2001 (Paper No. 2 ½) and 27 January 2003 (Paper No. 8) have been entered in full. Claims 1-44 are canceled. Newly presented claim 45 is directed to the elected invention and is under examination.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 45 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

- 1) claims 15 and 28-30 of U.S. Patent No. 4,810,643;

- 2) claim 5 of U.S. Patent No. 4,999,291; and
- 3) claims 1-4 of U.S. Patent No. 5,830,705.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

1) The instant claim differs from those issued in U.S. Patent No. 4,810,643 in that the instant claim is limited to a process for recombinant production of one of 11 distinct polypeptides, whereas the patented claims are directed to recombinant production of polypeptides shown in the Figures, or generic variants thereof. It is noted that patented claim 20 lists 10 of the 11 polypeptides recited in the instant claim. Therefore, it would have been obvious to recombinantly produce at least one of the polypeptides recited in the instant claim based on the sequences recited in the patented claims.

2) The instant claim differs from the claim issued in U.S. Patent No. 4,999,291 in that the instant claim is limited to a process for recombinant production of one of 11 distinct polypeptides, whereas the patented claim is directed to a process for recombinant production of a polypeptide limited only by the name "human pluripotent granulocyte colony-stimulating factor", also known as hpG-CSF. Using the specification of the patent in terms of a dictionary, it can be seen that hpG-CSF is shown in Table VII and differs from the [Met<sup>1</sup>] hpG-CSF recited in the instant claim only by removal of the leader sequence and additional of an N-terminal methionine. Such is routine in the art and would have been obvious to one skilled in the art to facilitate recombinant production of a mature form of the protein.

3) The instant claim differs from those issued in U.S. Patent No. 5,830,705 in that the instant claim is limited to a process for recombinant production of one of 11 distinct polypeptides, whereas the patented claims are limited to recombinant production of one of those polypeptides. See Figure 7 of '705, which is identical to [Met<sup>1</sup>] hpG-CSF recited in the instant claim. The patented species renders obvious the Markush Groups recited in the instant claim.

### ***Claim Objections***

Claim 45 is objected to because of the following informalities: there should be no period after "[Met]" recited in the claim. The first polypeptide should appear as "[Met<sup>1</sup>] hpG-CSF". Appropriate correction is required.

### ***Priority***

Applicant is advised that the first paragraph of the specification, claiming priority to several parent applications, has been amended by informal examiner's amendment as follows. The status of parent applications 09/430103 and 09/060275 has been updated to recite the patents into which the applications have matured. Also, there was an obvious clerical error in the serial number of the earliest filed parent application. It has been amended to read 06/768,959.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ECK  
March 18, 2003